

# Human/Animal Research

## Principles of Human Subjects Protection

There are three basic principles for the treatment of human subjects: autonomy, beneficence, and justice. These approximately correspond to the operational need for

- informed consent of subjects,
- reasonable ratios of benefits to risks, and
- equitable selection procedures and treatment.

Other concerns include:

- privacy/confidentiality concerns
- a plan for dealing with adverse effects
- the need to studies compare only treatments that are genuinely believed to be equally likely to have success
- Vulnerable populations must receive special attention to assure the appropriate application of these principles.

All human subjects research must be approved by the Institutional Review Board (IRB).

From [http://www.research.umn.edu/ethics/curriculum/human\\_subjects.html](http://www.research.umn.edu/ethics/curriculum/human_subjects.html).

**Case Study** At a residential treatment center for persons with mental retardation, lithium is frequently used to treat aggressive and self-injurious adolescents. However, this use of the drug has never been systematically tested on this population. Investigators propose a placebo-control experimental design but some staff members believe this is depriving patients of an established treatment.

Consider how the given principles might be applied in this case.

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**Animal Research** There are three guidelines for animal research:

- reduction in the numbers of animals used,
- refinement of techniques and procedures to reduce pain and distress, and
- replacement of conscious living higher animals with insentient material.

All animal research must be approved by the Institutional Animal Care and Use Committee (IACUC).

From “On Being a Scientist: A Guide to Responsible Conduct in Research: Third Edition”, by National Academy of Sciences.

**Case Study:** A researcher comes to you with two competing designs to test two pain relief medications in dogs. Dogs are given the medication and then poked with a electrical simulation. In one design, each dog gets both medications and is tested twice. In the other design, each dog only gets one medication and so is test only once. What principles come into play?

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*From the news...*

<http://www.health.umn.edu/nytimes>

In 2008, the University of Minnesota, Harvard University and the University of Iowa participated in a study to evaluate the effectiveness of Seroquel for treatment of borderline personality disorder (BPD). Harvard eventually dropped out of the study due to inability to recruit participants. The Harvard researcher said their inability to recruit patients was due to Massachusetts’ health reform and the high rate of insurance in the state, not due to issues with the trial.

In 2010, two subjects in Minnesota were enrolled in the study after responding to a flyer. The men were convicted sex offenders on probation and living in Alpha House, a halfway house in Minneapolis. They were screened using a well-established tool and found to meet all criteria for the study, so they were enrolled.

One of the men worked in the Alpha House kitchen and decided to crumble the study medication into the oatmeal he served for breakfast. Residents who ate the oatmeal reported feeling drowsy. When Alpha House determined what happened, the two men were dropped from the study and one of them returned to prison because he violated the terms of his probation.

Name: \_\_\_\_\_

What principle for animal/human research was new or most interesting to you? Describe what you learned about it.

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